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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,424	11/17/2003	Gai Ling Li	25350	4527
<div>20529 7590 09/14/2007</div> <div>NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314</div> <div>EXAMINER CLAYTOR, DEIRDRE RENEE</div> <div>ART UNIT PAPER NUMBER</div> <div>1617</div> <div>MAIL DATE DELIVERY MODE</div> <div>09/14/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/713,424

Applicant(s)

LI ET AL.

Examiner

Renee Claytor

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7,9 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7,9 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments to the claims and arguments filed on 7/19/2007 have been considered. The cancellation of claims 1, 8 and 10-15 is acknowledged and claims 2-7, 9 and 16 are being examined herein.

Applicant's amendments to the claims by clarifying what the donor phase is, is sufficient to overcome the 35 USC 112, second paragraph over claims 7-8 and 11-16 and that rejection is hereby withdrawn.

Applicant's amendments to the claims by making claims 2-7 and 16 dependent on claim 9 is sufficient to overcome the 35 USC 112, second paragraph rejection and the 35 USC 101 rejection over claims 1-8 and 10-16 and the rejection is hereby withdrawn.

Applicant's arguments over the 35 USC 103 rejections have been considered. Applicants argue that the Lauterback et al. reference, which was used to teach transdermal delivery of rotigotine hydrochloride, only teaches transdermal delivery of rotigotine in the free base form. The Examiner has considered this argument and it is found persuasive. Therefore, the 35 USC 103 rejection over Lauterback et al. in view of Panchagnula et al. and Suzuki et al. is hereby withdrawn.

However, there is prior art available teaching the transdermal delivery of rotigotine and a chloride salt of which is being given in the following new grounds of rejection. Applicants argue that even if it were obvious to combine the above references, there would not be a reasonable expectation of success in iontophoretic delivery of rotigotine because the dopamine agonists R-apomorphine and ropinirole

Art Unit: 1617

have not been successful in iontophoretic devices. However, R-apomorphine and ropinirole are structurally different from rotigotine; therefore, it cannot be assumed that because rotigotine is a dopamine agonist it will not be effective in an iontophoretic device.

The following new rejection over claims 2-7, 9 and 16 is give below.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 6-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US Patent 6,884,434) in view of Panchagnula et al. (Curr Op Chem Biol 2000, 4:468-473) and Suzuki et al. (US Patent 6,416,503).

Muller et al. teach a transdermal therapeutic system comprised of rotigotine in the hydrochloride form (see Col. 1, lines 9-25 and Examples 3-7). It is further taught that this transdermal therapeutic system is used for the treatment of Parkinson's disease (Col. 1, lines 9-10).

Muller et al. does not teach treating Parkinson's disease transdermally by application of an iontophoretic device, the concentration of rotigotine, the concentration of the chloride salt with a pH of 4 to 6.5 or the specific chloride salts as claimed in claims 4 and 5.

Panchagnula et al. teaches that iontophoretic transport involves movement of molecules across the skin (see second and third paragraph in column 2, page 468). Table 1 shows iontophoretic products under development, one of which includes a wearable iontophoretic patch (page 469). In addition it is further taught that a hydratable gel pad is also useful (last paragraph page 470).

Suzuki et al. teach iontophoretic drug devices that contain sodium chloride (Col. 7, lines 1-3).

Furthermore, it is obvious to vary and/or optimize the amount of rotigotine, amount of chloride salt and pH provided in the composition, according to the guidance provided by Muller et al. and Suzuki et al. to provide a composition having the desired properties such as the desired concentrations of rotigotine, chloride salt and pH in order to effectively construct an iontophoretic device that will effectively transfer drug through the skin. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Muller et al., which teach a method of treating Parkinson's disease with a transdermal patch containing rotigotine hydrochloride, with the teachings of Panchagnula et al., which teach transdermal delivery of drugs via iontophoresis, including a patch and Suzuki et al. which teach the use of sodium chloride in an iontophoretic device. One would have been motivated to use iontophoresis as a method to transdermally deliver rotigotine hydrochloride because

Art Unit: 1617

it is an efficient method to deliver drugs and cost effective (as taught by Panchagnula et al.) and to add sodium chloride in an effort to further improve drug delivery (as taught by Suzuki et al.).

Conclusion

Claims 5 and 16 are rejected because they are dependent on rejected claims.

No claims or allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER